NOV 1 4 2001

510(K) SUMMARY

N.E.S.S. NEUROMUSCULAR ELECTRICAL STIMULATION SYSTEMS LTD.
HANDMASTER

K012823

Applicant: N.E.S.S. Neuromuscular Electrical Stimulation Systems Ltd.
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Keidar Center
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P.O. Box 2500
Industrial Zone
Ra'anana, 43465
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Contact Persons:
Jonathan S. Kahan, Esq.
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Columbia Square
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Washington, DC 20004-1109
Tel: (202) 637-5794
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Trade Name: Handmaster

Common/Usual Name: External Functional Neuromuscular Stimulator

Classification Name: Powered Muscle Stimulator and External Functional Neuromuscular Stimulator

Predicate Devices

N.E.S.S. Neuromuscular Electrical Stimulation Systems Handmaster (K952273, K982482, and K010837); DanMed, Inc. AM800 Automove Electrical Muscle Stimulator (K972997).

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Intended Use

The Handmaster is intended to be used for the following indications: Maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation. In patients suffering from upper limb paralysis due to C5 spinal cord injury or hemiplegia due to stroke, it is also intended to provide hand active range of motion and hand function.

Device Description

The Handmaster is a portable, one-channel electrical neuromuscular stimulator for personal use. The stimulator serves five surface electrodes held on to the upper limb by a splint. The control unit housing the stimulator may be worn using the shoulder strap provided, or it may be placed on any stable surface. The splint is worn on the hand and forearm. The splint is connected to the control unit by a light cable.

A single channel of constant-voltage symmetrical biphasic Russian waveform stimulation is delivered to the muscles through five surface electrodes. Microprocessor-controlled switching of the stimulation between these five electrodes allows the muscles to be activated in combinations either cyclically or continuously. The stimulation is ramped up at the beginning and down at the end of each cycle.

The electrode locations allow the Handmaster to give finger and thumb extension and flexion. The user can select from five stimulation programs by pressing the mode button on the control unit. The active mode is displayed by a light glowing next to the labeled mode. When the device is stimulating, the light flashes. The stimulation programs are supplied as microprocessor firmware. They comprise either cyclic or continuous activation of the finger and thumb extensors and flexors.

The user can increase or decrease the stimulation intensity in ten discrete levels by pressing on buttons labeled "+" or "-" on the control unit. This alters the duration of the stimulation pulse. The intensity is displayed as a number (0 to 9) on a seven-segment display.

During the initial system set-up, the clinician opens a clinical panel within the control unit. Adjustments are provided for limiting the maximum current to the extensor muscles and to the flexor muscles, along

with a global timing factor which increases or decreases the duration of the stimulation cycles, effectively speeding or slowing the cyclic hand motion.

The user starts or stops the stimulation program by pressing a "trigger" button. If required, the user may also stop all stimulation immediately by switching OFF the device.

The Handmaster splint is used to hold the wrist joint at a comfortable extension angle (20°), and also to hold the electrodes on the forearm and hand segments. It is constructed from fiber-reinforced plastic with soft polyurethane cushion sections to distribute stress over bony regions. The electrodes are made from metal foil coated with carbon-impregnated polymer. Replaceable water-soaked cloth pads are arranged over the electrodes to provide a conductive interface with the skin. A sponge-capped bottle is provided to facilitate wetting of the electrode pads.

Rechargeable nickel-cadmium batteries power the device. Battery status can be displayed both during device operation and while recharging the batteries. Both visual and audio battery-low warnings are provided. It is necessary to disconnect splint/electrodes in order to recharge the batteries, as the same socket is used for both.

Performance Data & Substantial Equivalence

The Handmaster subject of this submission is exactly the same device in all aspects to the market-cleared Handmaster. The only difference between the devices is the expansion of the indication to include the ability of the Handmaster to provide hemiplegic patients with active range of motion and hand function. This expansion is supported by clinical data that demonstrates that the Handmaster can be safely and effectively used for this indication, like for the other device indications, without presenting any unreasonable risk of illness or injury. Therefore, the Company believes that substantial equivalence has been demonstrated without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Representing N.E.S.S., Ltd.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K012823
Trade/Device Name: Handmaster
Regulation Numbers: 21 CFR 890.5850 and 21 CFR 882.5810
Regulation Names: Powered Muscle Stimulator and External Functional Neuromuscular Stimulator
Regulatory Class: Class II
Product Codes: IPF and GZI
Dated: August 16, 2001
Received: August 16, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

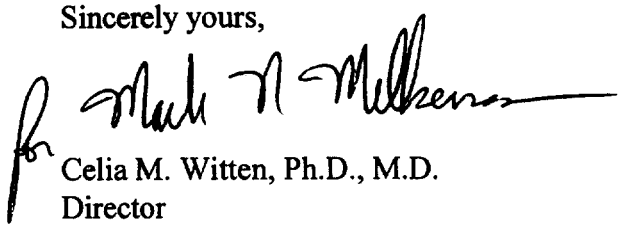
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 4 2001

INDICATIONS FOR USE STATEMENT

510(k) Number: K012823

Device Name:

Handmaster

Indications for Use:

The Handmaster is intended to be used for the following indications: Maintenance or increase of range of motion, reduction of muscle spasm, prevention or retardation of disuse atrophy, muscle reeducation, and increasing local blood circulation. In patients suffering from upper limb paralysis due to C5 spinal cord injury or hemiplegia due to stroke, it is also intended to provide hand active range of motion and hand function.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012823

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

7-7 for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012823

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